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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,726	12/02/1999	DAVID M READ	52951-USA-7A	2987

7590

08/18/2003

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/453,726

Applicant(s)

READ, DAVID M

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

**This non-final rejection is in response to the RCA/Amendment received on 06/25/2003**

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-2, 4-6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Davies et al (U.S.P.N. 4,863,627).

With respect to claims 1 and 10, Ignacio et al discloses a hydrogen peroxide sterilization indicator (col.5, lines 53-55) including the following: a substrate (col.4, lines 14-15 and figure, 40), an indicator composition disposed thereon (figure, 51), a binder (col.3, lines 40-41), and colorants that do not change color upon contact with hydrogen peroxide vapor (col.3, lines 54-56). In addition, Ignacio et al discloses various types of colorants and that hydrogen

Art Unit: 1744

peroxide can be in liquid or vapor state (examples 1-4), but fails to disclose such colorants as included in claims 1 and 10. However, Davies et al discloses that brilliant green is used as an indicator (col.4, lines 18-19) in hydrogen peroxide sterilization processes (col.1, lines 5-8). Thus, it would have been obvious to one having ordinary skill in the art to modify the colorants of Ignacio et al to include brilliant green since such a colorant is known to change colors in the presence of hydrogen peroxide (Davies et al, col.4, lines 15-19).

With respect to claims 2, 4-5, as discussed with respect to claims 1 and 10, Davies et al discloses the use of brilliant green as a colorant in hydrogen peroxide processes.

With respect to claims 6 and 9, Ignacio et al discloses colorants that do not change color upon contact with hydrogen peroxide vapor (col.3, lines 54-56) and the substrate is a polyester film (col.3, lines 64-65).

4. Claims 3, 7, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Davies et al (U.S.P.N. 4,863,627) and further in view of Bealing et al (U.S.P.N. 5,990,199).

With respect to claims 3, 7, and 21, both of Ignacio et al and Davies et al fail to disclose such colorants. With respect to claim 7, Bealing et al discloses Janus green B dye (col.6, line 26). However, with respect to claims 3 and 21, Bealing et al teaches various classes of colorant acid blue that can be used (col.6, lines 36-38). For example, Bealing et al uses acid blue #7 or acid blue #20. Alkali blue 6B is also known as acid blue #119. Also, Bealing et al provides only examples (col.6, lines 32-38) of using various classes of the colorant acid

Art Unit: 1744

blue. Thus, it would have been obvious to one having ordinary skill in the art to substitute one class of acid blue for another as taught by Bealing et al (col.6, lines 32-38).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,287,518) in view of Davies et al (U.S.P.N. 4,863,627) and further in view of Bealing et al (U.S.P.N. 5,990,199) and Barrett (U.S.P.N. 5,955,025).

With respect to claim 8, Ignacio et al and Davies et al both fail to disclose the use of alkali blue 6B and quinacridone red 19. Bealing et al discloses various classes of colorant acid blue can be used (col.6, lines 36-38). For example, Bealing uses Acid blue #7 or Acid blue #20. Alkali blue 6B is also known as Acid blue #119. Since Bealing provides only examples (col.6, lines 32-38) of using various classes of the colorant acid blue, choosing a different class of acid blue (i.e., Acid blue #119) is not non-obvious and is well within the scope of the artisan. However, fails to disclose the use of Quinacridone red 19. Barrett discloses the use of Quinacridone red (col.4, table). Barrett does not disclose the use to Quinacridone red 19. However, the significance of "19" is not understood by the examiner. It would have been obvious to one having ordinary skill in the art to modify the binder composition of Ignacio et al to include any of the available and known class or classes of acid blue dyes including acid blue #119 and Quinacridone red to indicate when a particular article has been subjected specifically to vaporous hydrogen peroxide for sterilization (Barrett, col.2, lines 58-61).

Art Unit: 1744

6. Claims 11, 16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Malchesky et al (U.S.P.N. 5,518,927).

With respect to claim 11, Ignacio et al discloses a method (columns 5-6) of monitoring a hydrogen peroxide sterilization process (abstract, lines 4-6) by exposing an article and the indicator (col.5, lines 20-22) to a sterilant vapor consisting essentially of hydrogen peroxide such that the indicator includes a substrate and a composition (abstract, lines 1-2) disposed thereon (col.1, lines 29-31). Ignacio et al discloses various colorants (col.2, lines 6-8), but fails to teach colorants mentioned in claim 11. In addition, Malchesky et al discloses that the indicator can be used in monitoring various sterilants in gaseous and liquid states (col.3, lines 30-32) such that hydrogen peroxide in vapor state is known in the art of sterilization. Malchesky et al discloses the use of crystal violet as a colorant (col.5, lines 60-65). Thus, it would have been obvious to one having ordinary skill in the art to modify Ignacio et al method to include crystal violet since crystal violet changes color when exposed to large class of known sterilants (Malchesky et al, col.5, lines 61-65 and col.3, lines 30-32).

With respect to claims 16 and 19-20, Ignacio et al discloses the following: one colorant that does not change upon contact with hydrogen peroxide vapor (col.1, lines 33-36), the substrate is a polyester film (col.3, lines 20-22), and the binder is shellac (col.2, lines 41-43).

Art Unit: 1744

7. Claims 12-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Malchesky et al (U.S.P.N. 5,518,927) and further in view of Ignacio et al (U.S.P.N. 6,287,518).

With respect to claims 12-13 and 15, both Ignacio et al and Malchesky et al fail to disclose colorants included in such claims. However, Ignacio et al discloses the use of thionin as a colorant in monitoring hydrogen peroxide vapor sterilization processes. Thus, it would have been obvious to one having ordinary skill in the art to modify Ignacio et al method to include thionin since such a dye changes color upon exposure to hydrogen peroxide vapor (Ignacio et al, col.6, lines 12-15 and col.5, lines 53-55).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Malchesky et al (U.S.P.N. 5,518,927) and further in view of Ignacio et al (U.S.P.N. 6,287,518) and Davies et al (U.S.P.N. 4,863,627).

With respect to claim 14, Ignacio et al, Malchesky et al, and Ignacio et al all fail to disclose colorants included in claim 14. However, Davies et al teaches that Brilliant green is used a colorant in hydrogen peroxide sterilization processes. Thus, it would have been obvious to one having ordinary skill in the art to modify Ignacio et al method to include brilliant green, which changes color when exposed to hydrogen peroxide (Davies et al, col.4, lines 15-19 and abstract, lines 1-6).

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Malchesky et al (U.S.P.N.

Art Unit: 1744

5,518,927) and further in view of Ignacio et al (U.S.P.N. 6,287,518) and Bealing et al (U.S.P.N. 5,990,199).

With respect to claim 17, Ignacio et al, Malchesky et al, and Ignacio et al all fail to disclose colorants included in claim 17. However, Bealing et al discloses the use of Janus Green B (col.6, line 26). Thus, it would have been obvious to one having ordinary skill in the art to modify Ignacio et al method to include Janus Green B since it is a known colorant in monitoring hydrogen peroxide sterilization processes (Bealing et al, col.5, lines 42-45 and col.6, line 26).

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Malchesky et al (U.S.P.N. 5,518,927) and further in view of Ignacio et al (U.S.P.N. 6,287,518), Bealing et al (U.S.P.N. 5,990,199), and Barrett (U.S.P.N. 5,955,025).

With respect to claim 18, Ignacio et al, Malchesky et al, and Ignacio et al all fail to disclose the use of alkali blue 6B and quinacridone red 19. However, Bealing et al discloses various classes of colorant acid blue that can be used (col.6, lines 36-38). For example, Bealing uses Acid blue #7 or Acid blue #20. Alkali blue 6B is also known as Acid blue #119. Since Bealing et al provides only examples (col.6, lines 32-38) of using various classes of the colorant acid blue, choosing a different class of acid blue (i.e., Acid blue #119) is not non-obvious and is well within the scope of the artisan. Bealing et al fails to specifically disclose the use of Quinacridone red 19. Barrett discloses the use of Quinacridone red (col.4, table). Barrett does not disclose the use to Quinacridone red 19. However, the significance of "19" is not understood by the examiner.

Art Unit: 1744

Thus, it would have been obvious to one having ordinary skill in the art to modify the composition of Ignacio to include any of the available and known class or classes of acid blue dyes including acid blue #119 and Quinacridone red to indicate when a particular article has been subjected specifically to vaporous hydrogen peroxide for sterilization (Barrett, col.2, lines 58-61).

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio et al (U.S.P.N. 6,063,631) in view of Nagata et al (U.S.P.N. 6,267,242) and further in view of Bealing et al (U.S.P.N. 5,990,199) and Davies et al (U.S.P.N. 4,863,627).

With respect to claim 23, Ignacio et al discloses a hydrogen peroxide sterilization indicator including a substrate and an indicator composition (abstract, lines 1-6) disposed thereon (col.1, lines 29-31) such that the indicator contains the following: a binder (col.2, lines 41-43), an optional colorant that does not change color upon contact with hydrogen peroxide (col.1, lines 33-36), an optional dispersing agent (col.2, lines 49-52), and an optional opacifying agent (col.3, lines 7-8). However, Ignacio et al fails to disclose that the indicator composition includes the following: an optional surfactant, an optional plasticizer, an optional antifoam agent, an optional basic material, and the colorants included in claim 23. Nagata et al discloses that the indicator composition includes an optional plasticizer (col.3, line 17) and an optional basic material (col.3, lines 9-10), but fails to teach the following: an optional surfactant, an optional antifoam agent, and the colorants included in claim 23. Bealing et al discloses that the indicator composition includes an optional surfactant (col.7, line 26), an optional

Art Unit: 1744

antifoam agent (col.7, line 24), but fails to disclose the colorants included in claim 23. Davies et al teaches that Brilliant green is used as a colorant in hydrogen peroxide sterilization processes. Thus, it would have been obvious to one having ordinary skill in the art to modify Ignacio et al indicator to include brilliant green, which changes color when exposed to hydrogen peroxide (Davies et al, col.4, lines 15-19 and abstract, lines 1-6).

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-21 and 23 have been considered but are moot in view of the new ground(s) of rejection.

On page 13 of the response, applicant argues, "Ignacio et al (U.S.P.N. 6,287,518) fails to disclose a method of monitoring a hydrogen peroxide sterilization process, including exposing an article to be sterilized and a hydrogen peroxide sterilization indicator to a sterilant vapor consisting essentially of hydrogen peroxide as recited in applicant's claim 11 as amended". With respect to claim 11, Ignacio et al (U.S.P.N. 6,063,631) is applied to claims 11 and 23. This reference discloses a method of monitoring a hydrogen peroxide sterilization process, including exposing an article to be sterilized and a hydrogen peroxide sterilization indicator to a sterilant vapor consisting essentially of hydrogen peroxide (abstract, lines 1-6). With respect to apparatus claims 1 and 10, the Ignacio et al (U.S.P.N. 6,287,518) reference still teaches such limitations and the intended use of the indicator is irrelevant.

On page 14 of the response, applicant argues the rejection based on Ignacio et al in view of Malchesky et al with respect to the methylene violet and

Art Unit: 1744

safranine dyes in claims 4 and 14. Now, claims 4 and 14 are rejected using the Davies et al reference, which discloses using brilliant green as a colorant in hydrogen peroxide sterilization processes. Furthermore, claim 14 is rejected using Ignacio et al (6,063,631), which teaches a method of monitoring a hydrogen peroxide sterilization process, including exposing an article to be sterilized and a hydrogen peroxide sterilization indicator to a sterilant vapor consisting essentially of hydrogen peroxide (abstract, lines 1-6).

On page 15 of the response, applicant argues, "Claims 7 and 17 of the present invention recite the use of Janus green B as a colorant that does not change color upon contact with hydrogen peroxide". Janus green B in Bealing et al was added based on Ignacio et al teaching of addition of colorants that do not change color during the sterilization process (col.7, lines 17-19). Janus green B is a component disclosed in both the claims and Bealing et al, such that the claims teach that Janus green B does not change color, where as the Bealing et al reference teach that Janus green B change color. Both claims and reference teach of a dual function of such a component (i.e., Janus green B is capable of changing or not changing color). As a result, depending on the intended use of Janus green B, adding such a component to Ignacio's composition is obvious as disclosed by Ignacio et al.

On page 16 of the response, applicant argues, "Examples 2-4 of Bealing et al use Janus green B in the compositions. First, these examples include the use of a steam sterilization process, not a hydrogen peroxide sterilization

Art Unit: 1744

process". Bealing et al teaches that Janus green B is used as hydrogen peroxide monitor (col.5, lines 42-45).

On page 16 of the response, applicant argues, "Bealing et al fails to teach or suggest that Janus green B does not change color upon contact with hydrogen peroxide vapor". The claims NOT Janus green B disclose such a limitation. Both claims and reference teach of a dual function of such a component (i.e., Janus green B is capable of changing or not changing color). As a result, depending on the intended use of Janus green B, adding such a component to Ignacio's composition is obvious as disclosed by Ignacio et al.

On page 17 of the response, applicant argues, "there is no teaching or suggestion provided that alkali blue 6B may successfully be substituted for either acid blue #7 or acid blue #20". Bealing et al discloses various classes of colorant acid blue that can be used (col.6, lines 36-38). For example, Bealing uses Acid blue #7 or Acid blue #20. Alkali blue 6B is also known as Acid blue #119. Since Bealing et al provides only examples (col.6, lines 32-38) of using various classes of the colorant acid blue, choosing a different class of acid blue (i.e., Acid blue #119) is not non-obvious and is well within the scope of the artisan. Bealing et al explicitly teach (col.6, lines 32-33, "among others") that other classes of acid blue can be utilized as well.

With respect to claim 23 (newly added), the new various components of the indicator composition are disclosed in Ignacio (U.S.P.N. 6,063,631), Nagata et al (U.S.P.N. 6,267,242), and Bealing et al (U.S.P.N. 5,990,199). Davies et al

Art Unit: 1744

teaches that Brilliant green is used as a colorant in hydrogen peroxide sterilization processes.

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**Conclusion**

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
August 11, 2003

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